

REMARKS

This paper responds to the Office Action dated October 5, 2007. A one-month extension request is filed concurrently herewith, extending the deadline for response to February 5, 2008, and thus this response is timely. Claims 1-83 are pending in this application. Claims 1 and 3-49 have been rejected in the Office Action dated October 5, 2007. Claims 2 and 50-83 have been withdrawn from consideration. By this Amendment, Applicants have cancelled claims 4 and 5 without prejudice. Without conceding the correctness of the Office Action's rejections, but in order to expedite prosecution, Applicants have amended claims 1, 3, 6, 28-29, and 42 and added new claims 84-88. Support for these amendments and new claims can be found at, e.g., Zerbe et al. (5,948,430), which is incorporated by reference as indicated at page 5 of priority provisional patent application 60/426,598 and also discussed at pp. 2-3 of the present specification. Support is also found in examples I and III on pp. 13 and 16 of the present specification and throughout the specification and claims as originally filed.

The specification has been amended pursuant to CFR §1.57(a) to include the inadvertently omitted incorporation by reference of the Zerbe et al. patent, which was included in the priority provisional patent application 60/426,598 at page 5, paragraph 3. Reconsideration and allowance in view of the following amendments and remarks are requested.

Rejections - 35 USC §102

Claims 1, 3, and 28 stand rejected under 35 USC § 102(e) as being anticipated by Barkalow et al. (US 2004/0096569). Claims 1 and 3 have been amended to recite "a powder matrix coating," incorporating a limitation of previous claim 4, which was not deemed to be anticipated by Barkalow. Barkalow does not disclose a bilayer film

having a film layer and a powder matrix coating. Additionally, with respect to claim 1, Barkalow does not disclose a powder matrix coating "comprising at least one composition selected from the group consisting of oils herbs, and tree and plant components and extracts." Thus, the rejected claims are not anticipated by Barkalow and Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 1, 3-7, 16, 17, 20-32, 36-39, and 42-45 stand rejected under 35 USC § 102(b) as being anticipated by Brown et al. (WO 98/20863; published as US 6,783,768). The Office Action states that Brown teaches a film layer and a coating in the form of powder material. The Office Action also contends that the film layer dissolving time is an inherent characteristic of the film ingredient. Applicants respectfully disagree.

Claims 1, 3, 28 and 42 have been amended to recite "wherein the film layer comprises at least one softener." Brown does not teach a rapidly dissolving film layer wherein the film layer comprises at least one softener and is coated with a powder matrix coating. For the above reason, the pending claims as amended are not anticipated by Brown and Applicants respectfully request that this rejection be reconsidered and withdrawn.

Rejections - 35 USC §103

Claims 1, and 3-49 stand rejected under 35 USC § 103(a) as being obvious over Brown in view of Barkalow et al.

The Office Action concedes that Brown does not teach using pullulan, carrageenan, stearic acid, carboxymethylcellulose, lipid, starch, a medicant such as menthol, or a sweetener such as talc. The Office action contends that such elements are supplied by the teachings of Barkalow and that it would have been obvious to

incorporate such ingredients into Brown's composition because a person of skill in the art would have been motivated to make such modifications because the ingredients are commonly used in the art of edible film and Barklow suggested powder coating can be used at [0065]. Applicants respectfully disagree for the following reasons.

First, as stated *supra*, Barkalow does not teach a powder matrix coating for application to a rapidly dissolving film layer. Accordingly, contrary to the Office Action, Barkalow does not supply any of the above missing elements as ingredients for a powder matrix coating in accordance with claims 10-15, 18-19, or 46-49. Thus, these claims are not rendered obvious by the cited art.

Second, contrary to the assertion made at page 6 of the Office Action, paragraph [0065] of Barkalow does not suggest the use of a powder coating to be applied to at least one side of a rapidly dissolving film layer. Instead, Barkalow at paragraphs [0062]-[0065] describes different processes for forming edible thin films and one such process involves applying a solution to a suitable carrier and drying the solution to form a film. The carrier material is described as being impermeable to the film coating such that the film coating disperses evenly onto the carrier and can be easily removed from the carrier. [0063]. Subsequently, paragraph [0065] describes a particular method of casting or applying a film on a carrier by stating, "[t]he casting or applying of the solution onto a suitable carrier material can be performed using any conventional coating technique. Examples of coating techniques include...powder coating." Thus, Barkalow does not suggest the use of a powder matrix coating to be applied to at least one side of a rapidly dissolving film layer as claimed, but instead describes a powder coating which is used to form the film layer itself. Accordingly, the present claims are not rendered obvious by the cited art.

Additionally, the Office Action has not pointed to any section in Brown or Barkalow disclosing a powder matrix coating for a rapidly dissolving film layer as claimed, which comprises "an absorption composition" (recited in claim 12) or the specific absorption compositions elected, e.g., carboxymethylcellulose or modified starches (claim 13).

For the above reasons, the present claims as amended are not rendered obvious by Brown in view of Barkalow. Thus, Applicants respectfully request that the rejections be reconsidered and withdrawn.

Applicants further submit that Brown or Barkalow do not anticipate nor render obvious the subject matter of new claims 84-88.

In view of the foregoing, it is submitted that the claims are in condition for allowance. A Notice of Allowance is requested.

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Respectfully submitted,

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